Remarks

The examiner's reconsideration of the application is requested in view of the amendments above, which are intended to address all of the matters raised by the examiner, as well as the comments which follow bellow.

It appears that there are some fundamental differences, over the interpretation of the teachings of the prior art, and that the Examiner has misunderstood certain of the arguments submitted in the last response. In view of this, and of the "final" status of the Office Action, if the application is not allowed, the Examiner is requested to contact the undersigned for an interview.

A set of amended claims is submitted for consideration by the Examiner, which, it is believed, help to clarify the differences between the present invention and the cited prior art. In the claims, Claim 1 has been amended to indicate that the device is an AST disk (a feature of the previous Claim 5), the machine readable information comprises a code of one or more letters and one or more numerals (substantially corresponding to Claim 4) and that the orientation means comprises means other than said code (as claimed in previous Claim 2). Claims 2, 4 and 5 are cancelled and Claims 6, 9, 10 and 11 have been amended for the sake of consistency with Claim 1. Claim 12 has been amended to indicate that the Image Analysis System is for use with AST plates each of which holds a plurality of devices each in accordance with Claim 1 and that the term "carrier device(s)" is replaced by "disk(s)". Claim 13 has been amended to indicate that the system determines the size of the zone of inhibition surrounding any AST disk. The other amendments to Claims 15 and 18 and are for the sake of consistency with Claim 1.

The Examiner has rejected Claim 1 under 35 U.S.C. §103 as being unpatentable over Berndt, US 5595708. For the following reasons, it is believed that this rejection does not hold in respect of the proposed amended Claim 1.

First, the Examiner has indicated that the "carrier device" shown in Berndt is the element (32) of figure 7 of that document. This element is a sample vial, not an AST disk as required by Claim 1. The applicants must also emphasize that the sample vials of Berndt do not contain any antibiotic related to a test to be carried out. Such an antibiotic is another feature of Claim 1. The Examiner argues that one of ordinary skill in the art would know that detecting bacteria growth would indicate whether an antibiotic is effective or not against a particular bacteria (see item 2 of the final action). That is not the case.

Antibodies and antibiotics are clearly not the same thing and the applicants question if the Examiner did indeed intend to refer to an antibody, not an antibiotic. The Examiner appears to infer that Berndt discloses vials which do contain antibiotics, (since he does not acknowledge that a lack of antibiotic is a difference between Berndt and Claim 1), but provides no explanation as to how this inference has been drawn.

It is respectfully submitted that Berndt could only actually disclose vials which have antibiotics in them if there is an explicit indication in Berndt that this is the case or if the use of antibiotics in the vials can reasonably be inferred as an inevitable requirement for the tests described in Berndt. Berndt contains no such explicit indication, and does not appear to describe any particular type of test that inevitably requires an antibiotic. On the latter point, it should be borne in mind that the growth of bacterial in a culture is dependent on a number factors, not just whether antibiotics are present or effective.

Antibiotics are not mentioned in Berndt as a factor relating to growth, probably because the system described in that patent relates to culturing micro-organisms from blood samples to determine infection, not to establish treatment profiles. Thus, in Berndt, the absence of bacterial growth could be related to any one of a number of possible factors, for example presence or absence of bacteria in the sample in the first place, or the efficacy of the chosen culturing process in enabling that bacteria to multiply, other than the presence or absence of any antibiotics.

The applicants thus maintain that Berndt does not disclose or suggest a system in which antibiotics are contained in its vials. In any case, Berndt quite manifestly fails to show an AST disk as now required by Claim 1.

Claim 1 also now specifies that the code which identifies the antibiotic takes the form of letters and one or more numerals. As the Examiner indicates, Berndt uses bar codes which are associated with the sample vials. Referring back to item 2 of the second action, it was not the applicants' intention to suggest that the bar code could not be read by the station: the response to the first action contained the statement that "adjacent to the sensor is a bar code which cannot can be read by the station". The word "cannot" should not have been included and the applicants apologize for any confusion which this error has caused. The point made the bar code shown in Berndt does not contain any information related to an antibiotic, however, stands.

Unlike the bar codes, the machine readable code of an AST disk according to Claim 1 which can be read by a person (as well as a machine) are able to comply with the WHO standards referred to in page 1 of the present application.

Turning to the orientation markings, the applicants have at no stage denied that a bar code can provide some orientation information and have to say that it is not clear to them how the Examiner has reached the contrary conclusion in the paragraph bridging pages 2 and 3 of the second action. The response to the first action indicated that any orientation information which is provided by a bar code is incorporated into the code itself, and cannot therefore constitute means other than the machine readable information embodied by the bar code.

The Examiner asserts that the reference indicia referred to in column 2 lines 36-40 of Berndt constitutes orientation means other than the machine readable information. The only reference indicia actually described in Berndt is a plain circle. This circle is concentric with the sensor bar code patterns. An orientation marking for a code must enable the code to be properly orientated, i.e. the correct angular position of the code to be determined. A concentric circle

quite plainly cannot provide any such orientation information, and is not therefore an orientation marking.

The Examiner also states that the bar code (234) in figures 8 and 9 of Berndt constitute an orientation marking. This clearly ignores the point made in the response to the first action that the bar code 234 is mounted on the tipping tray, whereas the bar codes 212/84 are mounted on the vial. There is therefore no relationship between the orientation of the bar code 234 and that of the bar code on the vial, so that the bar code 234 cannot provide any orientation information about the other bar code and does not therefore constitute an orientation marking.

The other assertion made by the Examination about Berndt is that it would have been obvious to use this system in the process of antibiotics susceptibility testing (AST). However antibiotics susceptibility testing is an internationally recognized standard procedure which has been evolved using carrier devices usually in the form of membrane disks (AST disks) used in conjunction with Petri dish plates containing a layer of solid growth medium such as agar gel.

Although the solid growth medium is not a feature of the claims of the present application (as the Examiner states), the point remains that a system which can only be used to analyze bacterial growth in liquid samples, such as the system of Berndt, is not suitable for use in AST because the inhibited growth of bacterial (if any) would occur through the whole sample in a liquid, whereas AST requires a localized zone of inhibition to be created so that its size can be measured, and thus requires that the bacteria be grown on a solid culture medium on which antibiotic is present to varying degrees dependent on the distance from the AST disk resting on the medium. Thus it is submitted that it would not have been obvious to use Berndt in AST testing.

Even if Berndt were to be used in such testing, the resultant device would rely on bar codes without any other form of orientation means, as the machine readable code, and so would still lack the particular type of machine readable code and orientation means required by Claim 1.

With regard to Wivelseip this does not relate the same technical field as Berndt. Furthermore since Berndt does not show any form AST system, is not appropriate for such a system and could not obviously be modified to function as an AST system, a combination of the teachings of Berndt and Wevelsiep would not produce an AST disk according to Claim 1.

It therefore submitted that Claim 1 is both novel and non-obvious over Berndt. The dependent claims are submitted to be, as well, by virtue of their dependency.

Turning to independent Claim 12, the applicants strongly refute the assertion that the apparatus shown in Graessle is equivalent to an AST system. Graessle is only suitable for counting bacteria colonies on a succession of culture substrates, whereas an image analysis system for interpreting AST plates needs to be able to detect individual AST disks on each plate and determine the presence or absence of any region of inhibited bacteria growth around each such disk.

Graessle does not show any type of electronic information processing means which would locate an AST disk on a plate from among a plurality of AST disks. Certainly, the sequential supply of substrates to the imaging position in Graessle cannot be considered remotely similar to the location of an AST disk on an image of a plate having a plurality of such disks.

The only code read in Graessle is the bar code 58 on each substrate. This code appears in the same position on each substrate, and each substrate is fed into the imagining position in the same orientation. Thus, in the system shown in Graessle, all of the bar codes will be in the same position and orientation when the substrates which carry them are at the imaging position. There is therefore no need to include any type of orientation marking for the bar codes. Thus there is no reason why Graessle would be combined with Tsuchiya. Even if such a combination were to be made the resultant system would not be an image analysis system for interpreting AST plates.

In addition to the allowability of Claim 12, it is pointed out that Claim 13 is novel and non-obvious over Graessle and Tsuchiya in its own right. Claim 13 now refers to the image analysis system determining the size of the zone of inhibited bacteria growth around a given AST disk. The applicants note that the Examiner does not appear to understand how a zone of inhibition can surround a located AST disk. Initially, the antibody will be held entirely on the disk, but will subsequently diffuse from the disk into the surrounding growth medium. This is explained more fully in page 1 of the present application.

With all due respect to the Examiner, the reference to AST disk is not the mere use an abbreviation as suggested in page 3 of the second action. In that connection, the vial shown in Amaral is used to contain a sample mixed in with one antibiotic, whereas an AST disk holds just the antibiotic, and allows that substance to migrate onto a solid sample on which other AST disks (possibly with other concentrations or types of antibiotic), are provided so that the disks define regions of a given sample in which the interaction between the bacteria on the sample and the antibiotics on the disks can be analysed. AST disk diffusion actually visualizes the growth of the organism of the plate and enables the zones of clearing of read due to sensitivity to antibiotics, or not if the organism is resistant to the antibiotics. This is quite different from the systems shown in either Berndt or Amaral.

Finally, regarding independent Claim 18, it is pointed out that Berndt does not lend itself to useful antibiotic susceptibility testing, and can only measure activity in a pre-defined region (i.e. the content of a given vial). Berndt cannot detect let alone interpret any region of visibly altered micro-organism growth in the vicinity of any susceptibility testing device. Nor, for the reasons explained above, can Berndt be used with an AST disk according to Claim 1. The unsuitability of Berndt for AST processers is not remedied by any combination with Wevelsiep.

The applicants therefore believe that the Examiner's rejections of the claims as currently worded should be retracted, and the application allowed. Such action is thus solicited.

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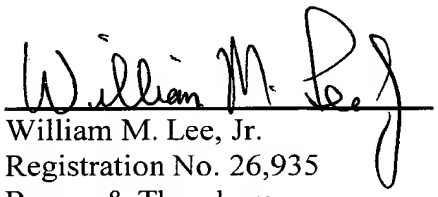
Respectfully submitted,



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